

NON-INVASIVE HYDRATION MONITORING



PhiloMetron, Inc.™

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ABOUT THE COMPANY

PhiloMetron, Inc.

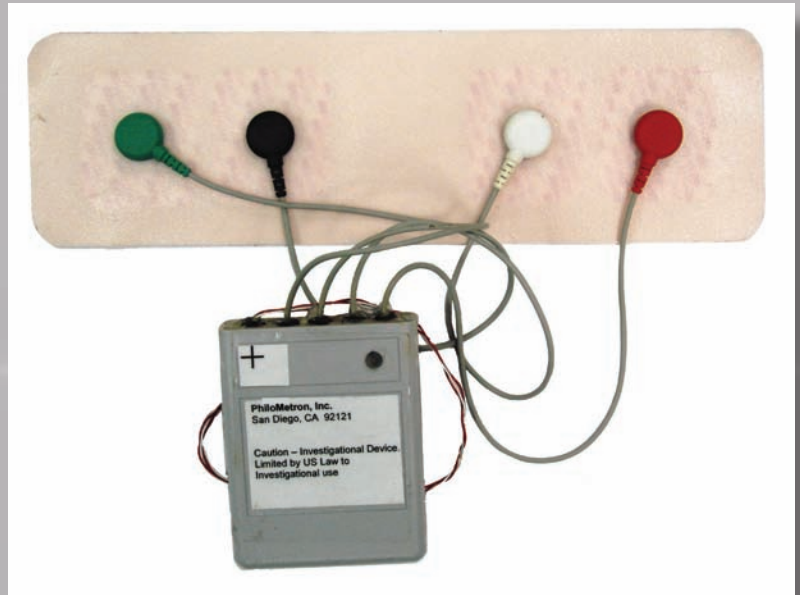
Founded 2000 - Darrel Drinan, CEO.

PhiloMetron is a healthcare company developing proprietary wireless diagnostic and therapeutic solutions, providing higher quality physiological information that are focused on improving the quality and lowering the cost of human health management.

Spinout
companies
raised
more than
\$50 million

VALUE PROPOSITION

Preventing dehydration and heat stress in ambulatory soldiers through remote human sensing.



A wearable, non-invasive, ambulatory hydration monitoring system

TECHNICAL CHALLENGE ADDRESSED

Warfighters must maintain adequate levels of hydration to retain their physical and cognitive skills in combat and training environments. Low levels of hydration affect cognitive perception and decision making, impact overall physiological performance and can even jeopardize survival. Consequently, it is essential that hydration levels be continuously monitored and alerts be provided to warn of low hydration levels. Prior to PhiloMetron's work on this DARPA SBIR, the primary methods available to measure dehydration used point-in-time diagnostic sampling methods to measure body weight, plasma osmolality, or urine osmolality. Plasma and urine osmolality measure the amount of solutes, such as salt, in the fluids. Such point-in-time diagnostic methods are impractical for applications where the person is ambulatory. Instead, methods that provide continuous, real-time detection and warning of a dangerous dehydration level are needed.

TECHNOLOGY DESCRIPTION

Prior to the successful completion of PhiloMetron's SBIR project (2004-2006), a wearable, non-invasive, ambulatory hydration monitoring system with a clinical sensitivity of less than 500 ml had not been successfully developed and validated. Detection of hydration changes of less than 500 ml sensitivity is critical in order to allow proactive re-hydration prior to serious physical or cognitive performance degradation. A typical military recruit may experience fluid loss as high as one to two liters per hour in training exercises preparing for combat.

During the two phases of this SBIR award, PhiloMetron developed and clinically validated an



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ambulatory hydration monitoring platform with the requisite sensing technology algorithms to enable use in a combat environment. The monitoring platform sensing technology measures the change of tissue hydration (fluids) in the lower chest region and was validated in this program to be highly correlated with the overall systemic hydration change. The monitoring system is sensitive enough to detect the onset of dehydration and provide alerts in sufficient time to avoid performance degradation and possible heat stroke.

Volunteers for the clinical study were selected from civilians reflecting the U.S. military recruit population. The study was conducted at a private, professional sports training facility. Several patents covering numerous applications in military and commercial markets were filed prior to the study. The monitoring platform is contained in a patch that may be worn for periods up to seven days. Additional sensors for such physiological functions as heart rate, temperature, motion, blood oxygen, etc. can be integrated, as required, for various applications. Physiological data can be transmitted by wireless methods to a local data collection and display unit (e.g., a cell phone or personal digital assistant [PDA]-like device) to alert the user or a third party of the need to take immediate, responsive action.

LESSONS LEARNED & BEST PRACTICES

- To increase volunteer recruitment rates, use recruiters of the same ethnicity as the ethnic cohorts being sought for the study.
- Allow sufficient time (nine months in PhiloMetron's case) to receive medical protocol approval from the cognizant clinical study protocol human subject safety review board.
- Delay the creation of a commercialization spinoff company until the technology is sufficiently ready for a marketable product.

ECONOMIC IMPACT

- Successfully created spinoff companies that use the technology developed in this program and employ more than 60 people.
- Raised more than \$50 million in venture capital investments for these spinoffs.
- Credibility gained from successful financing of spinoffs enhances the company's ability to obtain future financing.

APPLICATIONS

In addition to military applications, PhiloMetron's ambulatory hydration monitoring platform can be used to monitor and alert firefighters, athletes, the elderly, and patients in hospitals. The company's platform has been integrated into a congestive heart failure (CHF) monitoring system, which detects excess fluid accumulation in patients.

The platform is also being applied into a system addressing fitness and obesity. This system inputs physiological measurements to algorithms that calculate a person's caloric intake and expenditure. The system was validated through post-hoc analysis of the clinical study data.

PARTNERING & COLLABORATION

PhiloMetron's commercialization approach is to create spinoff companies to market its technologies for specific, targeted applications. Two spinoff companies have been established that apply technology derived from the DARPA SBIR work in the CHF monitoring and obesity/fitness markets.

For the CHF market, Corventis™ (www.corventis.com) offers an ambulatory monitoring platform that integrates technology for physiological sensing, wireless transmission, and Web services. Web services provide a hosted application for data analysis and storage, and a Web site for physiological trends and clinical information to aid in interpretation and diagnosis. When the system detects an abnormal event, it collects and sends the measured physiological data, e.g. electrocardiogram (ECG) etc. to one or more authorized persons. The company is distributing this system through cardiologists and hospitals.

Another spinoff company yet to be named officially, is integrating the hydration monitoring technology into an obesity/fitness application to provide a substantially more accurate and algorithmically derived measurement of caloric intake and expenditure. The system provides metabolic data to assist athletes and dieters in meeting their training and weight-management goals.